



10-27-06

PATENT APPLICATION

ITF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Feige et al.

Serial No.: 10/645,784

Group Art Unit No.: 1639

Filed: August 18, 2003

Examiner: Teresa D. Wessendorf

For: MODIFIED PEPTIDES AS THERAPEUTIC AGENTS

Docket No.: A-527E

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION OR NOTICE
OF ALLOWANCE (37 CFR 1.97(c))

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

It was drawn to our attention in the Office Action of April 21, 2006 (a response to which was submitted, via facsimile, on October 23, 2006) that certain articles listed in the PTO 1449 submitted on August 18, 2003 were "Not on File" and had not been reviewed by the Examiner. Although the Applicants' records indicate that the references were submitted in a related application, they submit them here as a courtesy. As a means of complying with the duty of disclosure, applicants submit a "List of References Cited by Applicant" on a modified PTO-1449 form. Copies of the cited references are enclosed for consideration by the Examiner.

This Information Disclosure Statement is being filed after three months of the filing date of this patent application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last, but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,
whichever occurs first.

Applicants make no determination of relevancy with respect to the reference submitted herewith and request the Examiner to make an independent determination of relevance and/or materiality of this reference.

Please charge Deposit Account No. 01-0519 in the amount of \$180.00 (37 CFR 1.97(c)). An original and one copy are enclosed.

10645784

10/27/2006

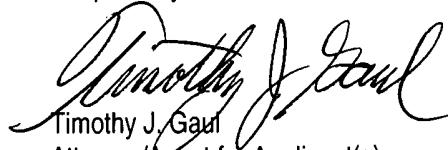
WABDEL1

00000062

010519

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 01-0519.

Respectfully submitted,



Timothy J. Gaul
Attorney/Agent for Applicant(s)
Registration No.: 33, 111
Phone: (805) 447-2688
Date: October 25, 2006

Please send all future correspondence to:

US Patent Operations/ TJG
Dept. 4300, M/S 28-2-C
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

Modified Form PTO-1449

Atty. Docket	A-527E	Serial No.
Applicant	Feige et al	
Filing Date	August 18, 2003	Group 1639



LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CA	Adey et al. (1996), 'Identification of calmodulin-binding peptide consensus sequences from a phage-displayed random peptide library', <i>Gene</i> 169:133-134.
CB	Adey et al. (1997), 'Isolation of peptides from phage-displayed random peptide libraries that interact with the talin-binding domain of vinculin', <i>Biochem. J.</i> 324:523-528.
CC	Ahern et al. (1990), 'Special Report: The Peptide-Oligonucleotide Partnership', <i>The Scientist</i> 4 (19):24-25.
CD	Akeson et al. (1996), 'AF12198, a Novel Low Molecular Weight Antagonist, Selectively Binds the Human Type I Interleukin (IL)-1 Receptor and Blocks in vivo Responses to IL-1', <i>J. Biol. Chem.</i> 271:30517-30523.
CE	Ball et al. (1997), 'Cell-cycle arrest and inhibition of Cdk4 activity by small peptides based on the carboxy-terminal domain of p21 ^{WAF1} ', <i>Current Biology</i> 7:71-80.
CF	Barna et al. (1994), "Combination therapy with a synthetic peptide of C-reactive protein and interleukin 2: augmented survival and eradication of pulmonary metastases," <i>Cancer Immunol. Immunother.</i> 38:38-42.
CG	Bhatnagar et al. (1996), 'Structure-Activity Relationships of Novel Hematoregulatory Peptides', <i>J. Med. Chem.</i> 39:3814-3819.
CH	Böttger et al. (1997), 'Molecular Characterization of the hdm2-p53 Interaction', <i>J. Mol. Biol.</i> 269:744-756.
CI	Böttger et al. (1996), 'Identification of novel mdm2 binding peptides by phage display', <i>Oncogene</i> 13:2141-2147.
CJ	Brocks et al. (1997), "A TNF Receptor Antagoistic scFv, Which is Not Secreted in Mammalian Cells, is Expressed as a Soluble Mono- and Bivalent scFv Derivative in Insect Cells," <i>Immunotechnology</i> 3(3): 173-184.
CK	Burstein et al. (1988), 'Thymic Humoral Factor γ2: Purification and Amino Acid Sequence of an Immunoregulatory Peptide from Calf Thymus', <i>Biochemistry</i> 27:4066-4071.
CL	Capon et al. (1989), 'Designing CD4 Immunoadhesins for AIDS Therapy', <i>Nature</i> 337:525-531.
CM	Chan and Kim (1998), "HIV Entry and Its Inhibition" <i>Cell</i> 93:681-684.
CN	Chirinos-Rojas et al. (1998), 'A Peptidomimetic Antagonist of TNF-α-Mediated Cytotoxicity Identified from a Phage-Displayed Random Peptide Library', <i>Journal of Immunology</i> 161:5621-5626.
CO	Cooper et al. (1987), 'Purification and characterization of a peptide from amyloid-rich pancreases of type 2 diabetic patients', <i>PNAS</i> 84:8628-8632.
CP	Cortese et al. (1996), 'Selection of biologically active peptides by phage display of random peptide libraries', <i>Current Opinion in Biotechnology</i> 7:616-621.
CQ	Couet et al. (1997), 'Identification of Peptide and Protein Ligands for the Caveolin-scaffolding Domain', <i>The Journal of Biological Chemistry</i> 272 (10):6525-6533.
CR	Couet et al. (1997), 'Interaction of a Receptor Tyrosine Kinase, EGF-R, with Caveolins', <i>The Journal of Biological Chemistry</i> Vol 272 (48):30429-30438.
CS	Cuthbertson et al. (1997), 'Design of Low Molecular Weight Hematoregulatory Agents from the Structure-Activity Relationship of a Dimeric Pentapeptide', <i>J. Med. Chem.</i> 40:2876-2882.
CT	Cwirla et al. (1997), 'Peptide Agonist of the Thrombopoietin Receptor', <i>Science</i> 276:1696-1699.
CU	Dedman et al. (1993), 'Selection of Targeted Biological Modifiers from a Bacteriophage Library of Random Peptides', <i>The Journal of Biological Chemistry</i> 268 (31):23025-23030.
CV	Devlin et al. (1990), 'Random Peptide Libraries: A Source of Specific Protein Binding Molecules', <i>Science</i> 249:404-406.
CW	Duncan et al. (1988), 'Localization of the binding site for the human high-affinity Fc receptor on IgG', <i>Nature</i> 332:563-564.

EXAMINER:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Modified Form PTO-1449		Atty. Docket	Serial No.
		A-527E	10/645,784
LIST OF REFERENCES CITED BY APPLICANT		Applicant	
(Use several sheets if necessary)		Feige et al	
Filing Date	August 18, 2003	Group	1639

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CX	Dyson et al. (1995), 'Selection of peptide inhibitors of interactions involved in complex protein assemblies: Association of the core and surface antigens of hepatitis B virus', <i>Proc. Natl. Acad. Sci. USA</i> 92:2194-2198.
CY	Fahraeus et al. (1996), 'Inhibition of pRb phosphorylation and cell-cycle progression by a 20-residue peptide derived from p16CDKN2/INK4A', <i>Current Biology</i> 6:84-91.
CZ	Fairbrother et al. (1998), 'Novel Peptides Selected to Bind Vascular Endothelial Growth Factor Target the Receptor-Binding Site', <i>Biochemistry</i> 37:17754-17764.
C1	Fisher et al. (1996), 'Treatment of septic shock with the tumor necrosis factor receptor: Fc fusion protein', <i>N. Eng. J. Med.</i> 334(26):1697-1702.
C2	Francis, Gillian E. (1992), 'Protein modification and fusion proteins', <i>Focus on Growth</i> 3:4-11.
C3	Fukumoto et al. (1998), 'Peptide mimics of the CTLA4-binding domain stimulate T-cell proliferation', <i>Nature Biotechnology</i> . 16:267-270.
C4	Gan et al. (1988), 'Echistatin', <i>JBC</i> 263:19827-19832.
C5	Ghetie et al. (1997), 'Increasing the serum persistence of an IgG fragment by random mutagenesis', <i>Nature Biotechnology</i> 15:637-640.
C6	Gibbs et al. (1994), 'Pharmaceutical Research in Molecular Oncology', <i>Cell</i> 79:193-198.
C7	Gibbs et al. (1994), 'Farnesyltransferase Inhibitors: Ras Research Yields a Potential Cancer Therapeutic', <i>Cell</i> 77:175-178.
C8	Goodson et al. (1994), 'High-affinity urokinase receptor antagonists identified with bacteriophage peptide display', <i>Proc. Natl. Acad. Sci. USA</i> 91:7129-7133.
C9	Graf and Kastin (1986), "Delta-Sleep-Inducing Peptide (DSIP): An Update" <i>Peptides</i> 7:1165-1187.
C10	Harvill et al. (1995), 'An IgG3-IL2 fusion protein activates complement, binds Fc _Y RI, generates LAK activity and shows enhanced binding to the high affinity IL-2R', <i>Immunotech</i> . 1:95-105.
C11	Harwig et al. (1994), "Neutrophil Defensins: Purification, Characterization, and Antimicrobial Testing" <i>Methods Enzymology</i> 236:160-172.
C12	Herz et al. (1997), 'Molecular Approaches to Receptors as Targets for Drug Discovery', <i>J. of Receptor & Signal Transduction Research</i> 17(5):671-776.
C13	Hong et al. (1995), 'Protein ligands of the human adenovirus type 2 outer capsid identified by biopanning of a phage-displayed peptide library on separate domains of wild-type and mutant penton capsomers', <i>The EMBO Journal</i> 14:4714-4727.
C14	Hughes, David (1998), 'Therapeutic antibodies make a comeback', <i>Drug Discovery Today</i> 3(10):439-442.
C15	Inagaki-Ohara et al. (1996), 'Effects of a Nonapeptide Thymic Hormone on Intestinal Intraepithelial Lymphocytes in Mice Following Administration of 5-Fluorouracil ¹ ', <i>Cellular Immunology</i> 17:30-40.
C16	Inglot, Anna D. (1997), 'Classification of Cytokines According to the Receptor Code', <i>Archivum Immunologica et Therapie Experimentalis</i> 45:353-357.
C17	Jefferies, D. (1998), 'Selection of Novel Ligands from Phage Display Libraries: An Alternative Approach to Drug and Vaccine Discovery?', <i>Parasitology Today</i> 14(5):202-206.
C18	Jeffries et al. (1995), 'Recognition sites on human IgG for Fc receptors: the role of glycosylation', <i>Immunology Letters</i> 44:111-117.
C19	Jeffries et al. (1990), 'Molecular Definition of Interaction Sites on Human IgG for Fc Receptors (huFc _Y R)', <i>Molecular Immunology</i> 27(12):1237-1240.

EXAMINER:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Modified Form PTO-1449		
LIST OF REFERENCES CITED BY APPLICANT		
(Use several sheets if necessary)		
Atty. Docket	A-527E	Serial No. 10/645,784
Applicant	Feige et al	
Filing Date	August 18, 2003	Group 1639

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C20	Johnson et al. (1998), "Identification of a 13 Amino Acid Peptide Mimetic of Erythropoietin and Description of Amino Acids Critical for the Mimetic Activity of EMP1," <i>Biochemistry</i> 37(11): 3699-3710.
C21	Jones et al. (1998), 'Stromal Expression of Jagged 1 Promotes Colony Formation by Fetal Hematopoietic Progenitor Cells', <i>Blood</i> 92(5):1505-1511.
C22	Junghans, R.P. (1997), 'Finally! The Brambell Receptor (FcRB)', <i>Immunologic Research</i> 16(1):29-57.
C23	Kay et al. (1998), 'From peptides to drugs via phage display', <i>DDT</i> 3(8): 370-378.
C24	King et al. (1991), 'Modulation of Bone Marrow Stromal Cell Production of Colony Stimulating Activity by the Synthetic Peptide', <i>Exp. Hematol.</i> 19:481.
C25	King et al. (1995), 'Hematoregulatory Peptide, SK&F Induced Stromal Cell Production of KC Enhances CFU-GM Growth and Effector Cell Function', <i>Blood</i> 86(1):309a
C26	Kitamura et al. (1993), 'Adrenomedullin: A Novel Hypotensive Peptide Isolated from Human Pheochromocytoma', <i>BBRC</i> 192:553-560.
C27	Kluczyk et al. (1997), 'Immunomodulatory Activity of Oligopeptides Related to Interleukin 1 Receptor Antagonist Sequence', <i>Archivum Immunologicum et Therapiae Experimentalis</i> 45:427-433.
C28	Koivunen et al. (1999), 'Tumor targeting with a selective gelatinase inhibitor', <i>Nature Biotech.</i> 17:768-774.
C29	Kreeger, Karen Young (1998), 'Immunological Applications Top List of Peptide-Synthesis Services', <i>The Scientist</i> 10(13):19-20.
C30	Laerum et al. (1988), 'The Dimer of Hemoregulatory Peptide (HP5B) Stimulates Mouse and Human Myelopoiesis in vitro', <i>Exp. Hemat.</i> 16:274-280.
C31	Linse et al. (1997), 'A Region of Vitamin K-dependent Protein S That Binds to C4b Binding Protein (C4BP) Identified Using Bacteriophage Peptide Display Libraries', <i>The Journal of Biological Chemistry</i> 272(23):14658-14665.
C32	Linsley et al. (1991), 'CTLA-4 is a Second Receptor for the B Cell Activation Antigen B7', <i>J. Exp. Med.</i> 174:561-569.
C33	Livnah et al. (1996), 'Functional Mimicry of a Protein Hormone by a Peptide Agonist: The EPO Receptor Complex at 2.8 Å', <i>Science</i> 273:464-471.
C34	Loetscher et al. (1993), "Efficacy of a Chimeric TNFR-IgG Fusion Protein to Inhibit TNF Activity in Animal Models of Septic Shock," <i>International Congress Series</i> 2: 455-462.
C35	Lowman, H.B. (1997), 'Bacteriophage display and discovery of peptide leads for drug development', <i>Annu. Rev. Biophys. Biomol. Struct.</i> 26:401-24.
C36	Lundergan et al. (1999), "Angiotensin-II increases cytoplasmic calcium, cell number and total DNA for human periodontal ligament cells in vitro" <i>J. Periodontal Res.</i> 34(4):223-228.
C37	Martens et al. (1995), 'Peptides which bind to E-selectin and block neutrophil adhesion', <i>The Journal of Biological Chemistry</i> 270(36):21129-21136.
C38	McGregor, Duncan (1996), 'Selection of proteins and peptides from libraries displayed on filamentous bacteriophage', <i>Molecular Biotechnology</i> 6:155-162.
C39	Moodie et al. (1994), 'The 3Rs of Life: Ras, Raf and Growth Regulation', <i>TIG</i> 10(2):44-48.
C40	Moonga et al. (1998), "Effects of Peptide Fragments of Protein Kinase C on Isolated Rat Osteoclasts" <i>Experimental Physiology</i> 83:717-725.
C41	Morikis et al. (1998), 'Solution structure of Compstatin, a potent complement inhibitor', <i>Protein Science</i> 7:619-627.

EXAMINER:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Modified Form PTO-1449		Atty. Docket	Serial No.
		A-527E	10/645,784
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)		Applicant	Feige et al
		Filing Date	Group
		August 18, 2003	1639

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C42	Naranda et al. (June, 1999), "Activation of erythropoietin receptor in the absence of hormone by a peptide that binds to a domain different from the hormone binding site," <i>Proc. Natl. Acad. Sci. USA</i> 96:7569-7574.
C43	Nishi et al. (1996), 'Tight-binding inhibitory sequences against pp60 ^{c-src} identified using a random 15-amino-acid peptide library', <i>FEBS</i> 339:237-240.
C44	Park et al. (2000), "Rationally designed anti-HER2/neu peptide mimetic disables P185 ^{HER2/neu} tyrosine kinases in vitro and in vivo" <i>Nature Biotechnology</i> 18:194-198.
C45	Pasquaimi et al. (1996), 'Organ targeting <i>in vivo</i> using phage display peptide libraries', <i>Nature</i> 380:364-366.
C46	Paukovits et al. (1984), 'Structural Investigations on a Peptide Regulating Hemopoiesis in vitro and in vivo', <i>Hoppe-Seylers Z Physiol. Chem</i> 364:303-311.
C47	Pawson et al. (1993), 'SH2 and SH3 Domains', <i>Current Biology</i> 3(7):434-442.
C48	Pierce et al. (1995), 'Identification of cyclized calmodulin antagonists from a phage display random peptide library', <i>Molecular Diversity</i> 1:259-265.
C49	Piette et al. (1997), "Mdm2: keeping p53 under control", <i>Oncogene</i> 15:1001-1010.
C50	Powis, Garth (1991), 'Signalling targets for anticancer drug development", <i>TiPS</i> 12:188-194.
C51	Rickles et al. (1994), 'Identification of Src, Fyn, Lyn, PI3K and AbI SH3 domain ligands using phage display libraries', <i>The EMBO Journal</i> 13(23):5598-5604.
C52	Rodriguez-Viciiana et al. (1994), 'Phosphatidylinositol-3-OH kinase as a direct target of Ras', <i>Nature</i> 370:527-532.
C53	Sahu et al. (1996), 'Inhibition of Human Complement by a C3-Binding Peptide Isolated from a Phage-Displayed Random Peptide Library ¹ ', <i>The Journal of Immunology</i> 157:884-891.
C54	Sarmay et al. (1992), 'Mapping and Comparison of the Interaction Sites on the Fc Region of IgG Responsible for Triggering Antibody Dependent Cellular Cytotoxicity (ADCC) Through Different Types of Human Fcγ Receptor', <i>Molecular Immunology</i> 29(5):633-639.
C55	Scott et al. (1990), 'Searching for Peptide Ligands with an Epitope Library', <i>Science</i> 249:386-390.
C56	Siemion et al. (1991), 'The Evidence on the Possible Interleukin-1α Tuftsin Competition', <i>Archivum Immunologiae et Therapiae Experimentalis</i> 39:605-611.
C57	Sparks et al. (1996), 'Distinct ligand preferences of Src homology 3 domains from Src, Yes, Abl, Cortactin, p53bp2, PLCγ, Crk, and Grb2', <i>Proc. Natl. Acad. Sci. USA</i> 93:1540-1544.
C58	Sparks et al. (1994), 'Identification and Characterization of Src SH3 Ligands from Phage-displayed Random Peptide Libraries', <i>The Journal of Biological Chemistry</i> 269(39):23853-23856.
C59	Stauffer et al. (1997), 'Inhibition of Lyn Function in Mast Cell Activation by SH3 Domain Binding Peptides', <i>Biochemistry</i> 36:9388-9394.
C60	Suzuki and Yoshino (1992), "The Relationship Between Amino Acid Sequences of Sperm-Activating Peptides and the Taxonomy of Echinoids" <i>Comp. Biochem. Physiol.</i> 102B:679-690.
C61	Takasaki et al. (1997), 'Structure-based design and characterization of exocyclic peptidomimetics that inhibit TNFα binding to its receptor', <i>Nature Biotechnology</i> 15:1266-1270.
C62	Van Zee et al. (1996), 'Protection Against Lethal Escherichia coli Bacteremia in Baboons (<i>Papio anubis</i>) by Pretreatment with a 55-kDa TNF Receptor (CD120a)-Ig Fusion Protein, Ro 45-2081', <i>J. Immunol.</i> 156:2221-2230.

EXAMINER:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Modified Form PTO-1449	Atty. Docket	A-527E	Serial No.
LIST OF REFERENCES CITED BY APPLICANT	Applicant	Feige et al	
(Use several sheets if necessary)	Filing Date	August 18, 2003	Group 1639

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.